DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m373n.pdf

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-85

September 24, 1997

Mr. Kevin J. Russell
President
Mastek, Inc.
1264 Cypress Avenue
Melbourne, FL 32935

Dear Mr. Russell:

We are writing to you because on September 9 and 10, 1997 FDA Investigator Ronald T. Weber collected information that revealed serious regulatory problems involving the radionuclide monitoring system which is manufactured and distributed by your firm.

Under the Federal Food, Drug and Cosmetic Act (The Act), this product is considered to be an accessory to a medical device used to treat a medical condition or to affect the structure or function of the body, and is therefore, considered to be a Class II device. The law requires that manufacturers of medical devices conform with the Quality System Regulations as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that the device is adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the Quality System Regulation. These violations include, but are not limited to the following:

- Failure to establish and implement an adequate complaint handling program, e.g., there are no records of failure investigations conducted, there is a lack of consistency in recording reported complaints.

- Failure to document, review, approve, implement and validate changes to components, finished devices, labeling, packaging or manufacturing process specifications, e.g., there are no change control specifications documented and approved for making and recording changes to devices, and to ensure all changes are verified or validated adequately.

- Failure to establish and document adequate procedures for changes to a specification, method, process, or procedure, e.g., available procedures do not stipulate who or what positions are required for approval and the mechanism for assigning an effective date.

- Failure to ensure finished devices meet all specifications prior to distribution, e.g., there are no records that document finished device testing was conducted or is adequate, there are no Device History Records (DHR) that document dates of manufacture, quantity manufactured, and quantity released.

- Failure to maintain written procedures required by the Quality Systems Regulation currently in use.

- Failure to conduct planned and periodic audits of the quality assurance program pursuant to written procedures.

Your device is also misbranded within the meaning of section 502(o) because a notice or other information respecting it was not provided as required by such section or section 510(k).

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 7200 Lake Ellenor Dr., Suite 120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the GMPs and does not necessarily address other obligations you have under the law. You may obtain general information about all the FDA requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about the Quality Systems Regulation requirements and how they affect your particular device, or about the content of this letter, please contact Tin Couzins at (407) 648-6823, ext. #264.

Sincerely,

Douglas D. Tolen
Director
Florida District

Enclosure